

## **REMARKS**

This is in response to the Office Action mailed July 10, 2008. This Response is intended to specifically address the Office's assertion that the Amendment filed March 24, 2008 was deemed not fully responsive for allegedly failing to address how claim 49, as amended to include the subject matter of claim 53, is patentable over the cited references (namely EP '192 to Goudaliez in further view of either US 3,864,265 to Markley or US 4,163,721 to Lobdell). Because the March 24, 2008 Amendment was not entered, all of the claim amendments and arguments presented in that Amendment are being re-submitted herein. Applicants have further amended claim 49 and also added arguments/remarks in this Response to more clearly distinguish over the cited references and to specifically address how amended claim 49 is patentable over the cited references.

### **Re-Submission of the Amendment filed March 24, 2008**

Claims 1, 4, 6-14, 16, 17, 19-22, 48-53, 55-59 and 65 are pending in the present application, of which claim 49 is independent. Claims 56-59 were previously withdrawn. At the outset, Applicants wish to thank the Examiner for accepting the drawings submitted on September 12, 2003.

In the Office Action, the Examiner 1) rejected claim 49, 9 and 55 under 35 USC 102(b) as being anticipated by EP Patent No. 1106192 (equivalent to US 7,060,183 to Goudaliez); 2) rejected claims 1, 4, 6-8, 11-13, 16-17 and 50-52 under 35 USC 103 as being unpatentable over EP '192 in further view of US 6,168,653 to Meyers or US 4,157,967 to Meyst or US 4,326,957 to Rosenberg or US 5,269,917 to Stankowski; 3) rejected claims 19-21 and 48 under 35 USC 103 as being unpatentable over EP '192 in further view of US 4,009,714 to Hammer; 4) rejected claim 22 under 35 USC 103 as being unpatentable over the prior art as

applied to claim 19 above, in further view of Published Application 2001/0009756 to Hei; 5) rejected claim 10 under 35 USC 103 as being unpatentable over EP '192 in further view of Meyst; 6) rejected claim 14 under 35 USC 103 as being unpatentable over the prior art applied to claim 13 above and in further view of US 4,453,927 to Sinko; 7) rejected claim 53 under 35 USC 103 as being upatentable over EP '192 in further view of either US 3,864,265 to Markley or US 4,163,721 to Lobdell and 8) rejected claim 65 under 35 USC 103 as being unpatentable over EP '192 in further view of US 6,364,864 to Mohiuddin.

Applicants respectfully submit that the pending claims are not anticipated and would not have been obvious in view of the prior art as set forth in detail below.

**Independent Claim 49 Is Not Anticipated by EP Patent No. 1106192 (equivalent to US 7,060,183 to Goudaliez)**

Applicants turn first to the rejection of independent claim 49 and the respective dependent claims under 35 USC 102(b) as being anticipated by EP Patent No. 1106192 (equivalent to US 7,060,183 to Goudaliez). Without acquiescing in the Examiner's rejection, Applicants have amended claim 49 to include the features of dependent claims 1, 6, 7, 8, 11, 21, 22 and 53. Accordingly, dependent claims 1, 6, 7, 8, 11, 21, 22 and 53 are being cancelled herein.

Specifically, claim 49, as amended, is directed to a flow-through device for removing selected compounds from a liquid. Amended claim 49 requires, among other things, a housing including a pair of side walls welded together near their peripheries to provide a peripheral end wall, said side walls and end wall defining a chamber. The housing includes at least one injection port in flow communication with the chamber. The housing also includes separate inlet and outlet ports communicating with the chamber. A compound

removal medium comprising a sintered medium comprising a particulate of a sorbent composition and a polymeric binder is located within the chamber between the walls.

Amended claim 49 further provides that the removal medium includes a peripheral end surface terminating interior to the peripheral end wall of the housing thereby defining a gap between the peripheral end surface and the peripheral end wall, wherein the removal medium peripheral end is in contact with a liquid impermeable barrier. The liquid impermeable barrier comprises an injectable material injected through the injection port. The material substantially fills the gap located between the peripheral end surface of the removal medium and the peripheral end wall of the housing. Amended claim 49 further recites a gripping member extending from at least one of the side walls and a sheet of filter material disposed between the compound removal medium and the housing side wall including the outlet port, wherein the outlet housing side wall comprises a nesting surface for supporting the filter and wherein the peripheral portion of the filter material is held at the nesting surface. The filter material is permeable to the liquid but substantially impermeable to the particulate of the compound removal medium.

Applicants respectfully submit that Goudaliez does not describe or suggest a flow-through device as presently claimed. In particular, Goudaliez does not disclose a flow-through device comprising (1) a housing with at least one injection port in flow communication with an interior chamber of the housing and (2) a liquid impermeable barrier comprising an injectable material which is injected through the injection port substantially filling the gap between a peripheral end surface of a removing medium and a peripheral end wall of the housing and (3) a compound removal medium comprising a sintered medium comprising a particulate of a sorbent composition and a polymeric binder located within a chamber

between housing walls and (4) a sheet of filter material (in addition to the compound removal medium) that is permeable to liquid but substantially impermeable to the particulate, disposed between a compound removal medium and a housing side wall including an outlet port, wherein an outlet housing side wall comprises a nesting surface for supporting a filter and wherein a peripheral portion of a filter material is held at a nesting surface. Nor does Goudaliez disclose a gripping member extending from at least one of the side walls and located radially interior to a tongue and groove and extending a sufficient distance from the side wall to contact a removal medium.

As described in the specification of the present published application and as shown in Figures 27 and 28, an injectable material, i.e. "sealant" 92 may be injected into the gap 90. Injection ports 94 may be provided in housing portions 44 and/or 46. The injectable liquid impermeable barrier, once injected into the gap, effectively seals the gap and prevents liquid from bypassing the removal media 60. Moreover, it allows for introduction of injectable material after the housing has been assembled. Injection of the barrier material allows it to flow into the gap 90 of housing chamber 42, and substantially filling the gap, thereby ensuring that the biological fluid cannot bypass the removal medium. See page 5, para. [0068] of the published application. These features are not found, and the above-described advantages are not achieved in Goudaliez.

In contrast, Goudaliez describes a filtering unit comprising a rigid outer casing. Goudaliez describes "association means" in the form of a bead of adhesive dispersed between the periphery of the filter and the inside face of the rigid wall. However, the rigid outer casing of Goudaliez does not include an injection port (separate from the inlet and outlet port) that is in flow communication with an interior chamber of a housing as set forth in

amended claim 49. Thus, it is clear that Goudaliez also does not disclose a liquid impermeable barrier that is injected through an injection port, thereby substantially filling a gap between a peripheral end surface of a removal medium and a peripheral end wall of a housing as presently claimed.

Further, Goudaliez does not disclose a flow through device for removing selected compounds from a liquid comprising a compound removal medium comprising a sintered medium comprising a particulate of a sorbent composition and a polymeric binder located within a chamber between housing walls as set forth in amended claim 49. In particular, and as described in the specification of the present application in further detail, the claimed flow through device generally, and the compound removal medium in particular, is capable of removing undesired components from biological fluid such as unreacted pathogen inactivation compound and by-products of a pathogen inactivation treatment. See paragraphs 76-79 of the published US application. In contrast, the prior art does not describe any type of compound removal medium capable of removing undesired components from biological fluid. In contrast, Goudaliez generally discloses a filter unit for filtering particles from fluid, and more specifically, leukocytes from blood. There is no teaching or suggestion, however, in Goudaliez of a compound removal medium comprising a sintered medium comprising a particulate of a sorbent composition and a polymeric binder as set forth in amended claim 49.

Finally, Goudaliez does not disclose a sheet of filter material that is permeable to liquid but substantially impermeable to the particulate, disposed between a compound removal medium and a housing side wall including an outlet port, wherein an outlet housing side wall comprises a nesting surface for supporting a filter and wherein a peripheral portion of a filter

material is held at the nesting surface. While Goudaliez discloses generally a “post filter layer,” it does not disclose or suggest that such a post filter layer is in addition to and in combination with a compound removal medium as presently claimed, and that is permeable to liquid but substantially impermeable to the particulate of the compound removal medium. There is also no teaching in Goudaliez that the “post filter layer” is held at a nesting surface for supporting a filter on an outlet housing side wall as set forth in amended claim 49.

Thus, for at least these reasons, Applicants submit that amended claim 49 and the respective dependent claims are not anticipated and would not have been obvious over Goudaliez.

**Amended claim 49 Would Not Have Been Obvious Over EP ‘192 in Further View of  
Either US 3,864,265 to Markley or US 4,163,721 to Lobdell**

The following additional arguments and/or remarks are intended to specifically address the Office Action mailed July 10, 2008 and any deficiency that may have existed in the Amendment filed March 24, 2008. Specifically, in the previous Office Action, the Examiner indicated that Markley and Lobdell disclose pre-forming a filter device and then injecting sealant via injection ports, and therefore, to include an injection port for a sealant in the Goudaliez filter device would have been obvious.

As discussed above, Goudaliez does not describe a flow-through device for removing selected compounds from liquid comprising (1) a housing with at least one injection port in flow communication with an interior chamber of the housing, (2) a liquid impermeable barrier comprising an injectable material which is injected through the injection port substantially filling the gap between a peripheral end surface of a removing medium and a peripheral end wall of the housing, (3) a compound removal medium comprising a sintered medium

comprising a particulate of a sorbent composition and a polymeric binder located within a chamber between housing walls, (4) a sheet of filter material that is permeable to liquid but substantially impermeable to the particulate that is disposed between a compound removal medium and a housing side wall including an outlet port, wherein an outlet housing side wall comprises a nesting surface for supporting a filter and wherein a peripheral portion of a filter material is held at the nesting surface and (5) a gripping member extending from at least one of the side walls and located radially interior to a tongue and groove and extending a sufficient distance from the side wall to contact a removal medium.

Further, amended claim 49 would not have been obvious over Goudaliez, either alone or in combination with Markley and/or Lobdell. In particular, Markley does not disclose subject matter missing from Goudaliez and is not properly combinable with Goudaliez to render the claimed subject matter obvious. Specifically, Markley is directed generally to a device employing a folded membrane for dialysis. However, Markley does not teach or suggest a flow-through device for removing selected compounds from a liquid comprising a compound removal medium comprising a sintered medium comprising a particulate of a sorbent composition and a polymeric binder located within a chamber between housing side walls. Instead, the membrane of Markley is a commonly used semi-permeable dialysis membrane formed of cellophane which allows the blood contaminants to pass through and into fresh dialysate fluid. Further, Markley does not teach or suggest a sheet of filter material permeable to a liquid but substantially impermeable to particulate of a compound removal medium that is disposed between a compound removal medium and a housing side wall including an outlet port, wherein an outlet housing side wall comprises a nesting surface for supporting a filter and wherein a peripheral portion of a filter material is held at the nesting

surface. While Markley discloses generally a pleated dialysis membrane, it does not disclose or suggest a sheet of filter material in addition to and in combination with a compound removal device that is permeable to liquid but substantially impermeable to the particulate of the compound removal device, and that is held at a nesting surface as presently claimed.

Similarly, Lobdell does not disclose subject matter missing from Goudaliez and is not properly combinable with Goudaliez to render the claimed subject matter obvious. In particular, Lobdell is directed generally to a device having a pleated membrane within a housing for dialysis. However, Lobdell does not teach or suggest a flow-through device for removing selected compounds from a liquid comprising a compound removal medium comprising a sintered medium comprising a particulate of a sorbent composition and a polymeric binder located within a chamber between housing side walls. Instead, the filter of Lobdell, like the filter of Markley, is an accordion pleated cellophane sheet commonly used in dialysis for filtering contaminants from blood.

Further, Lobdell does not teach or suggest a sheet of filter material permeable to a liquid but substantially impermeable to particulate that is disposed between a removal medium and a housing side wall including an outlet port, wherein an outlet housing side wall comprises a nesting surface for supporting a filter and wherein a peripheral portion of a filter material is held at the nesting surface. While Lobdell discloses generally a dialysis membrane, it does not disclose or suggest a sheet of filter material in addition to and in combination with a compound removal device that is permeable to liquid but substantially impermeable to the particulate of the compound removal device, as required by amended claim 49.



Applicants acknowledge that Hei et al. (US Application Publication No. 2001/0009756

A1) disclose a flow-through compound removal device including a disk of adsorbent particulate and polymeric binder. However, Hei does not disclose other explicitly recited features required by claim 49. Specifically, Hei does not disclose a flow-through device comprising (1) a housing including a pair of side walls defining a chamber wherein one side wall includes a continuous tongue near the periphery and another side wall comprises a continuous groove at or near the periphery for receiving the tongue, wherein the groove is defined by radial inner and outer walls, and wherein at least one of the walls includes a shoulder extending therefrom, whereby said shoulder is disposed relative to the tongue such that during assembly, the tongue initially contacts the shoulder, (2) a flow-through device wherein a housing includes at least one injection port (in addition to an inlet and an outlet) in flow communication with a chamber for injecting a liquid impermeable barrier comprising an injectible material which substantially fills a gap between a peripheral end surface of a compound removal medium and a peripheral end wall of a housing. Nor does Hei disclose a gripping member extending from at least one of the side walls and located radially interior to a tongue and groove and extending a sufficient distance from the side wall to contact a removal medium. None of these recited features required by amended claim 49 are described or suggested in Hei.

The flow-through device of claim 49 provides numerous advantages that have previously not been available in a single, flow-through, compound removal device. By providing a housing with rigid sidewalls that include a tongue and groove arrangement that can be firmly joined together, unintentional separation of the mating housing portions is substantially avoided, thereby ensuring that liquid (e.g., blood or other biological fluid) cannot

leak out of the device. Leakage and exposure of the blood product to the outside environment would result in spoilage of the blood product. In addition, the rigid housing of the claimed compound removal device protects the compound removal medium – which is a sintered disk of polymer and particulate – from damage by external forces that may occur during shipment and handling. Moreover, while providing a robust device, the claimed device also provides stability and effectual processing of the fluid within the device. For example, by including gripping members that extend from at least one of the side walls and contact the removal medium, the removal medium is fixed within the housing that is further stabilized by the firm joinder provided by the tongue and groove arrangement. The gripping members further assist in preventing liquid bypass which aspect is further enhanced by the inclusion of an injectable sealant that fills the areas between the compound removal medium peripheral end surface and peripheral end wall of the housing. In the end, what is provided is a robust and sturdy compound removal device.

While Applicants acknowledge that the prior art of record disclose some of the individual features (e.g., Markley/Lobdell – injection ports; Goudaliez – avoiding liquid bypass; Hei – a sintered compound removal device of polymer and particulate), Applicants respectfully submit that there is no reason why a skilled person would have arrived at the claimed device based on the leuko-reduction filter as taught by Goudaliez, a dialyzer device as taught by either Markely or Lobdell, or with the compound removal device of Hei. Even if such a combination were made, the claimed flow-through device for removing selected compounds from a liquid would still not be achieved. For example, even in Hei, which is the only reference that discloses a compound removal device, there is no appreciation for achieving the stability provided by the gripping members or inclusion of a sealant to avoid

liquid bypass. Conversely, while Goudaliez acknowledges the drawbacks of liquid bypass and Markley and Lobdell recognize the use of introducing a sealant (through injection ports) they are not burdened by the need to do so while holding in place a compound removal device. Further, “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art”. See *KSR International Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007).

Thus, Applicants submit that any combination of the cited art would rely largely on hindsight from the present application, the picking of individual features from numerous references, and, improperly using Applicant’s claimed invention as a hindsight blueprint to reconstruct the claimed invention by picking and choosing selected features from numerous isolated and quite different prior art references. Even in the post-KSR world, it remains improper to use hindsight in the evaluation of obviousness, or at the very least, the temptation to use hindsight should be resisted. “A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning”. *Id.*, at 1742. For at least these reasons, Applicants respectfully submit that claim 49, as amended to include the subject matter of dependent claims 1, 6, 7, 8, 11, 21, 22 and 53, would not have been obvious over Goudaliez either alone or in combination with Markley and/or Lobdell, or any of the other cited references.

**The Dependent Claims Are Not Anticipated and Would Not Have Been Obvious Over  
The Cited References**

The remaining dependent claims are all dependent from amended independent claim 49. For the reasons already stated hereinabove, amended claim 49 is not anticipated and

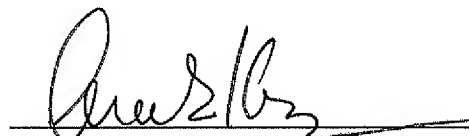
would not have been obvious over Goudaliez. Accordingly, Applicants submit that the claims dependent on claim 49 are also not anticipated and would not have been obvious over Goudaliez, either alone or in combination with any of the other the cited references.

### **Conclusion**

For the reasons set forth above, Applicants submit that the claims are not anticipated or obvious in view of the prior art, and are now in condition for allowance. Reconsideration and allowance of such claims are respectfully requested.

Date SEPTEMBER 9, 2008

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Andrew G. Kolomayets', written over a horizontal line.

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